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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,415	07/23/2003	Karl H. Weisgraber	UCAL-282	2272

24353 7590 07/05/2006

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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,415	WEISGRABER ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' amendment and remarks filed 17 April 2006 in response to Office Action mailed 25 January 2006 is acknowledged and entered.

2. Applicants are notified that the previous Office Action mailed 25 January 2006 is hereby vacated (See attached Interview Summary dated 21 June 2006) and the prosecution is re-opened in this application.

3. Applicants' arguments and remarks filed 17 April 2006 are fully and carefully considered, however, in view of the vacated previous Office Action cited *supra*, those remarks are moot.

4. Your application has been re-assigned to Art Unit 1655 at the United States Patent and Trademark Office (i.e., USPTO). The assigned Examiner to your application at the USPTO is Dr. Kailash. C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

Claims Status

5. Claim 21 is added.

6. Claims 5 and 12 are amended.

7. Claims 1-21 are pending.

Election /Restriction

8. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I, consisting of claims 1-4 and 21 drawn to a composition comprising an isolated apoE stable folding intermediate, classified under Class 424, subclass 94.63, for example.

- Group II, consisting of claims 5-11, drawn to a method to identify an agent that reduces the lipid binding activity of apoE stable folding intermediate, classified under Class 436, subclass 8 or 501, for example.

- Group III, consisting of Claims 12-15 drawn to a method to identify an agent that reduces the level of an apoE stable folding intermediate, classified under Class 435, subclass 4, for example.

- Group IV, consisting of Claims 16-20 drawn to a method to treat cardiovascular or neurological disease, classified under Class 430, subclass 50, for example.

Inventions are Independent Or Distinct

9. The inventions are distinct, each from the other because of the following reasons:

Invention in Group I is related to inventions in Groups II-IV as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case, the method of invention encompassed in invention of Group IV for e.g., can be accomplished with any composition that is available in a pharmaceutical enterprise and said composition reduces the activity of an apoE stable folding intermediate. Similarly, method inventions in Groups II-III would also be accomplished with any composition that would be applicable in determining the agent that reduces the lipid binding activity of an apoE stable folding intermediate or applicable to determine an agent to reduce the level of an apoE folding intermediate in a given system.

Inventions in Groups II-IV are unrelated to each other because each one of them is directed to different inventions that are not connected in design, components, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, for example invention recited in claims encompassed in Group III is directed to a method to identify an agent that reduces a composition's activity, whereas the method invention in Group IV is to treat a disease and the inventive Group II method identifies an agent to reduce the lipid binding activity of a composition. Thus, the methods in each of the inventions of Group II and III have a different effect from each other and the method of Group IV. Therefore, the methods claimed in inventions II-IV for e.g., may not be practiced together.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. This is because inventions in each one of the inventive Groups I-IV will require a different search strategy. Fir example to search invention in Group I one only requires to incorporate an isolated apoE stable folding intermediate in the strategy, whereas for inventive Group II one requires to

search for inhibitors and in inventive Group IV the treatment aspect for a disease will have to be incorporated in the strategy Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (i.e., Class and subclass), and their recognized diverse subject matter, they would illicit an undue burden on the examiner to search and examine all the inventions in groups I- VI in one single application. Furthermore, the criteria for patentability may not be same for each of the recited groups and what may be applicable for one group may not at all be applicable to other group. Thus, restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to different compositions comprised of a variety of ingredients. Said compositions are comprised of single ingredient (s) or mixtures of ingredients (e.g., yeasts of different genera and species grown under a variety of culture conditions).

The search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because of the fact that the inventive groups discussed above incorporate numerous compositions and numerous ingredients within each of the same, single composition. For example, to conduct a literature search for invention in Group IV that is constituted of different ingredients and mixtures thereof, one would be searching for a total number of combinations that will be a factorial of at least 6 with each one of the ingredients up to ingredient number 1 (i.e. 6*5, 6*4, 6*3, 6*2, 6*1). Thus, this group alone will exert an enormous search burden on the Examiner. Any additional groups to be considered would further increase the groups to a sum total of all the groups that will be a number of geometrical proportions. Therefore, if the applicant elects any one of Groups I-IX above, the applicant must also make election of species by electing a single species from each of the following categories:

Only one cardiovascular or neurological disease or Alzheimer's disease.

11. If applicant elects Group IV invention, the applicant is required under 35 U.S.C. §121 to elect a single disclosed species of disease, enumerating all ingredients therein for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 5, 12 and 16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR §1.116; amendments submitted after allowance are governed by 37 CFR §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patent Examiner
Art Unit 1655
(571) 272-0923

June 23, 2006

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200